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PATENT
Atty. Docket No.: BSC-009DV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT:	Crowley, R.	CONFIRMATION NO.:	4101
SERIAL NO.:	09/879,433	GROUP NO.:	3739
FILED:	June 12, 2001	EXAMINER:	David M. Shay
TITLE:	Mucosal Ablation		

BRIEF ON APPEAL
(CORRECTED)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a corrected version of an appeal brief from the rejection of claims 14-40 in a final Office action dated April 17, 2003 (hereinafter referred to as the "final Office action"). A Notice of Appeal was filed on July 16, 2003, pursuant to 37 C.F.R. § 1.191(a). An appeal brief with a petition for extension of time and the appropriate fees were submitted on October 16, 2003, with an Appendix and Exhibit A. A Notification of Non-compliance with 37 CFR 1.192(c) dated January 6, 2004, was subsequently issued in this case. In response, Appellant hereby submits a corrected version of the appeal brief where a typographic mistake on page 5, last full paragraph, is corrected to read "claim 14" instead of "claim 40." Appellant submits that this correction rectifies the non-compliance specified in the Notification.

Also submitted herewith is an Appendix presenting the claims on appeal, and Exhibit A presenting evidence of the real party in interest. The corrected Appeal Brief, Appendix, and Exhibit A are submitted in triplicate in accordance with 37 C.F.R. § 1.192(a).

(1) Real party in interest

The real party in interest in the above-identified patent application is Boston Scientific Corporation. An Assignment perfecting Boston Scientific Corporation's interest in this application was recorded by the U.S. Patent and Trademark Office on January 21, 2003, at

Reel/Frame 013675/0947. Copies of the Notice of Recordation of Assignment Document, a PTO-stamped Recordation Form Cover Sheet, and the Assignment, are attached as Exhibit A.

(2) Related appeals and interferences

To the best of the Appellant's knowledge, there are no related appeals or interferences.

(3) Status of claims

The application on appeal was initially filed with claims 14-33 through a Preliminary Amendment filed with the application (claims 1-13 were canceled by the same Amendment without prejudice). Claims 34-39 were added through a second Preliminary Amendment dated February 8, 2002. Claim 40 was added through an Amendment and Response dated January 13, 2003. Accordingly, claims 14-40 are currently pending and on appeal. The claims on appeal appear in the Appendix attached to this brief.

(4) Status of Amendments

No amendments were filed subsequent to the final Office action.

(5) Summary of invention

As defined by the claims on appeal, Appellant's invention relates to a method for ablating mucosal or endothelial lining. The method includes steps of providing a light device that includes a flash lamp (7), and inserting the light device inside a patient's body near a mucosal or endothelial lining that is on top of a muscle layer. See, e.g., Application, pg. 3, lns. 2-6; and FIG. 1. The method further includes steps of energizing the flash lamp (7) to generate a high intensity ultraviolet light and ablating the mucosal or endothelial lining with the generated light while avoiding causing substantial damage to the muscle layer underneath. See id. at pg. 9, lns. 15-20.

In one embodiment as defined by claim 31, the inventive method further includes a step of disposing a lens with a lenticular pattern in a pathway of the light generated by the flash lamp. See id. at pg. 6, lns. 18-20. In another embodiment as defined by claim 33, the inventive method

further includes a step of stepping up the voltage of the flash lamp's power supply. See id. at pg. 6, lns. 24-28.

(6) Issues

1. The first issue presented for appeal is whether instant claims 14-18, 21-25, 27, 28, 33-37, 39, and 40 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,053,033 to Clarke (hereinafter referred to as "Clarke") in view of U.S. Patent No. 5,405,369 to Selman *et al.* (hereinafter referred to as "Selman").

2. The second issue presented for appeal is whether instant claims 14, 19, and 37-39 are patentable under 35 U.S.C. § 103(a) over Clarke in view of U.S. Patent No. 5,814,041 to Anderson *et al.* (hereinafter referred to as "Anderson").

3. The third issue presented for appeal is whether instant claims 14-18, 20-25, 27-29, 33-37, 39, and 40 are patentable under 35 U.S.C. § 103(a) over Clarke in view of Selman, and further in view of U.S. Patent No. 5,899,882 to Waksman *et al.* (hereinafter referred to as "Waksman").

4. The fourth issue presented for appeal is whether instant claims 25-32 are patentable under 35 U.S.C. § 103(a) over Clarke in view of Selman and Waksman, and further in view of U.S. Patent No. 4,799,479 to Spears (hereinafter referred to as "Spears").

5. Although Appellant believes that the above-identified issues correspond to all of the pending rejections, Appellant also appeals any other bases for rejection of the pending claims which were not explicitly stated in the final Office action but which may be regarded as still pending.

(7) Grouping of claims

The claims on appeal 14-40 do not stand or fall together.

- Claims 14-30 and 37-40 stand or fall together.

- Claims 31 and 32 stand or fall together.
- Claims 33-36 stand or fall together.

Claims 14-30 and 37-40 recite methods of using high intensity ultraviolet light generated by a flash lamp to ablate the mucosal or endothelial lining. Claims 31 and 32 require, in addition to the use of flash lamp, placing a lens with a lenticular pattern in the light pathway. A lenticular pattern alters light distribution in a specific manner (Application, pg. 3, lns. 12-14; pg. 6, 18-20; and FIG. 1), which brings about non-obvious advantages in selective tissue ablation not specifically recited by other claims. Therefore, Appellant submits that claims 31 and 32 are separately patentable from all other claims.

Claims 33-36 require, in addition to the limitations recited by claim 14, stepping up the voltage of power supplied to the flash lamp, which adds new structural requirements, such as a transformer, besides the flash lamp (Application, pg. 6, ln. 24 to pg. 7, ln. 20). Such structural requirements add further strain to the limited space available for intracorporeal operation and present new challenges to the inventor. The additional step also brings non-obvious advantages to the invention, such as easier-to-produce light of short duration. Therefore, Appellant submits that claims 33-36 are separately patentable from all other claims. Further reasons why the three claim groups are separately patentable are set forth in Section (8) below where their patentability against the prior art is discussed separately.

(8) Argument

Appellant believes that the following arguments address each of the issues presented for appeal.

1. Claims 14-18, 21-25, 27, 28, 33-37, 39, and 40 are patentable under 35 U.S.C. § 103 over Clarke in view of Selman.

Appellant respectfully requests the reversal of the final rejections, under 35 U.S.C. § 103(a), of claims 14-18, 21-25, 27, 28, 33-37, 39, and 40. The combination of references cited by the Examiner fails to establish a *prima facie* case of obviousness with respect to the claims on appeal.

The sole independent claim on appeal, claim 14, recites a method for ablating mucosal or endothelial lining comprising the following steps:

a) providing a light device comprising a flash lamp;

b) inserting the light device inside a body near a mucosal or endothelial lining to be ablated, the mucosal or endothelial lining being on top of a muscle layer;

c) energizing the flash lamp to generate a high intensity ultraviolet light; and

d) ablating the mucosal or endothelial lining with the generated light, and avoiding causing substantial damage to the muscle layer underneath.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j).

The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (BPAI 1985). MPEP 706.02(j).

For reasons set forth more fully below, Appellant respectfully submits that (1) Clarke and Selman both teach away from their combination or modification in relation to the claims on appeal; (2) even if the two references are combined, they cannot be reasonably considered to teach or suggest step (d) of instant claim 14; and (3) Clarke and Selman do not teach or suggest the additional limitations recited in claims 33-36 either.

1.1 Clarke and Selman both teach away from combination or modification.

Clarke is concerned with preventing restenosis after angioplasty (col. 1, lns. 6-10). Clarke's methods are based on the belief that killing smooth muscle cells at an angioplasty site reduces the risk of restenosis (col. 2, lns. 39-50). Accordingly, Clarke's various embodiments

are designed to substantially reduce the amount of smooth muscle cells at the angioplasty site "while minimizing damage to surrounding tissue" (col. 2, lns. 47-50; see col. 5, lns. 6-9 and lns. 52-62). In contrast to the method recited in the instant claim 14, methods described in Clarke do not "damag[e] either the inner endothelium layer 22 or the outer adventitia 26 of the blood vessel" (col. 5, lns. 1-5) (emphasis added). Clarke also shows, through FIGS. 3A-3C, and 6A-6C, that the effect of ultraviolet (UV) radiation, aimed specifically at smooth muscle cells (40) in a muscle layer (24), is a marked reduction in the number of the smooth muscle cells (40), and in the thickness of the muscle layer (24) and the plaque layer (20) (col. 5, lns. 1-9, and 41-62). Moreover, those figures in Clarke show that the endothelial layer (22) remains unaffected by the treatment and retains largely the same thickness (see col. 5, lns. 1-5). The Examiner's interpretation of Clarke's text at column 5, lines 46-56, ignores the actual content of the figures that the cited text aims to describe (final Office action, pg. 4, lns. 13-20). In particular, contrary to step (d) recited in the instant claim 14, Clarke's methods neither ablate the mucosal or endothelial lining, nor avoid substantial damage to the muscle layer underneath. In fact, as explained above, just the opposite is the case: whereas claim 14 calls for ablation, Clarke's technique aims for preservation.

Selman describes photodynamic treatment of transplanted gastro-intestinal tissue to strip the transplanted tissue of mucus-producing functions (col. 1, lns. 54-68). Specifically, after the mucosal layer of the transplanted tissue takes up photosensitive compositions, the mucosal layer is destroyed when the photosensitive compositions absorb radiation energy; the submucosal and muscular layers, however, are spared (col. 3, lns. 44-52; col. 6, lns. 19-26). As the Examiner recognizes, Selman does not teach the use of a flash lamp as recited in the instant claim 14 (final Office action, pg. 2, lns. 6-7).

The teachings of Clarke and Selman cannot reasonably be combined so as to anticipate instant claim 14. Both references are very specific in teaching which layer needs to be destroyed to achieve their respective purposes, and the two references target layers that are mutually exclusive. In Clarke, the smooth muscle layer is destroyed while the mucosal layer is saved. Conversely, in Selman, it is the mucosal layer that is destroyed while the muscle layer is saved. Therefore, one skilled in the art, knowing that effective optical destruction of a specific tissue layer requires light of a specific wavelength (and hence, specific light devices), and knowing that

Clarke uses UV radiation to preserve exactly the layer that Selman destroys (Clarke, col. 5, lns. 1-5), would not utilize Clarke's flash lamp for Selman's purpose.

Nor does Selman motivate a skilled artisan to retain the UV-generating flash lamp in Clarke's method and to completely switch the target layer with the non-target layer. Not only would this switch represent precisely the opposite of what Clarke teaches, but also would defeat Clarke's objective. In particular, Selman does not provide evidence or theory that saving the smooth muscle layer and destroying the endothelial layer reduces risk of restenosis at an angioplasty site. Instead, Selman teaches that in place of the destroyed mucosal layer, "transitional epithelium cells migrate in from the surrounding tissue and repopulate or cover the transplant tissue segment" (col. 3, lns. 3-6), an effect that may contribute to hyperplasia and restenosis that Clarke sets out to remedy. Indeed, as Selman's teaching is limited to photodynamic treatment, it is not even clear how one might modify Clarke's method to target the mucosal or endothelial lining previously shown to be unaffected by Clarke's UV radiation (see Clarke, col. 5, lns. 1-5).

Accordingly, both Clarke and Selman, individually teach away from the invention recited in claim 14, and collectively teach away from their combination. Their teachings are antithetical.

1.2 Clarke and Selman, even if combined, do not teach or suggest instant claim 14.

Even if Clarke and Selman are combined, their teachings still fail to teach or suggest all the limitations recited in the instant claim 14.

Clarke describes the use of a flash lamp, but uses it to destroy the muscle layer that instant claim 14 expressly recites to preserve. In other words, to the extend Clarke teaches any utility of a flash lamp, the relevance of Clarke is constrained by its teaching of using UV radiation generated by the flash lamp destroy the muscle layer. Further, Clarke teaches ineffectiveness of UV radiation against the endothelium layer (col. 5, lns. 1-5), the target of instant claim 14.

Selman's method is able to ablate the mucosal layer while preserving the muscle layer because the two layers absorb different amounts of a photosensitive composition:

> "The electromagnetic radiation is absorbed by the photosensitive composition and causes a series of chemical reactions which leads to damage or destruction of the mucosal layer of tissue of the transplant bowel segment, while sparing the submucosal and muscular layers of the transplant tissue. The structures of the

> recipient organ (i.e. the walls, blood vessels and muscle layers) are not damaged because the photosensitive composition does not accumulate in these structures in sufficient amounts to cause damage."

Col. 3, lns. 46-59; see also, col. 8, lns. 28-31. With Clarke teaching the ineffectiveness of UV radiation against the endothelial lining, and Selman's teaching being limited to photodynamic treatment, a hypothetical combination of Clarke and Selman would still fail to provide an enabling description of the method recited by instant claim 14, which recites use of high intensity UV radiation generated by a flash lamp to ablate the mucosal or the endothelial lining.

For reasons stated in Sections 1.1 and 1.2, Appellant submits that instant claim 14 and its dependent claims are non-obvious over Clarke and Selman.

1.3 Clarke and Selman do not teach or suggest additional limitations of instant claim 33-36.

Claim 33 depends from claim 14, and claims 34-36 each depend from claim 33. Claim 33 recites:

> The method of claim 14, further comprising stepping up the voltage of power supplied to the flash lamp.

Stepping up the voltage of power supplied to the flash lamp helps to produce light waves of short duration, which is advantageous for purpose of the instant invention (Application, pg. 6, ln. 24 to pg. 7, ln. 20). Neither Clarke nor Selman teaches or suggests such a step in their methods. Accordingly, Appellant respectfully submits that instant claim 33 and its dependent claims 34-36 are non-obvious over Clarke and Selman for additional reasons stated here in Section 1.3.

2. Claims 14, 19, and 37-39 are patentable under 35 U.S.C. § 103 over Clarke in view of Anderson.

Anderson describes a method for producing a uniform pattern of illumination in laser-based photodynamic therapy in order to ablate the endometrium, i.e., the mucous membrane lining the uterus (col. 1, lns. 24-52; col. 5, lns. 10-47). As the Examiner recognizes, Anderson does not teach the use of a flash lamp, an element recited in the instant claim 14 (final Office action, pg. 2, lns. 15-17). Moreover, like Selman, Anderson describes a method that targets a tissue layer excluded by Clarke, namely, the mucous membrane. Accordingly, the skilled artisan

would also be dissuaded from combining the disclosure of Clarke and Anderson as the two references target mutually exclusive tissue layers.

The Examiner states that "[i]t would have been obvious to the artisan of ordinary skill to employ the method of Clark[e] to ablate the endometrium, since this is one of the tissues that responds to light ablation, as taught by Anderson..." (final Office Action, pg. 2, lns. 17-21). Appellant respectfully disagrees. Similar to Selman, Anderson's teaching is limited to improvement in photodynamic treatment. In other words, Anderson teaches that the endometrium responds to Photofrin treatment better than surrounding tissue including the myometrium, which is the smooth muscle of uterus (col. 1, lns. 46-52). Anderson does not teach that the endometrium responds to light ablation. Quite the opposite: Anderson teaches that the endometrium can be ablated if treated with a photosensitive composition that renders it vulnerable to ablation. Therefore, even if combined with Clarke, Anderson would fail to remedy Clarke's deficiency with respect to instant claim 14, i.e., teaching the ablating of the mucosal or endothelial lining with UV radiation while avoiding substantial damage to the muscle layer underneath.

For reasons stated above, Appellant submits that instant claim 14 and its dependent claims 19 and 37-39 are non-obvious over Clarke in view of Anderson, and respectfully requests the reversal of the final rejections under 35 U.S.C. § 103(a).

3. Claims 14-18, 20-25, 27-29, 33-37, 39, and 40 are patentable under 35 U.S.C. § 103 over Clarke in view of Selman and Waksman.

Waksman describes using a radioactive material to inhibit formation of scar tissue following balloon angioplasty (Abstract; col. 2, lns. 14-67). Waksman does not provide any teaching that remedies the deficiency of Clarke and Selman with respect to instant claim 14 or instant claim 33, as discussed above in Section 1.

First, Waksman echoes the teaching of Clarke and states that "formation of scar tissue by smooth muscle proliferation, also known as intimal hyperplasia, is believed to be a major contributor to restenosis following balloon angioplasty of the coronary artery" (col. 2, lns. 27-30). Nowhere in Waksman is it suggested that, to prevent restenosis, the tissue layer to be destroyed should exclude the muscle layer. Therefore, Waksman does not motivate one skilled in the art to modify Clarke's method and target the mucosal or endothelial lining while sparing

the muscle layer, as required by instant claim 14. Second, Waksman does not concern use of light, but use of radioactive materials as the energy source (col. 7, lns. 14-19, and 41-48). Accordingly, Waksman does not provide any suggestion as how to modify Clarke's method to ablate the mucosal or endothelial using UV light generated by a flash lamp, again, as required by instant claim 14. Third, Waksman does not teach or suggest stepping up the voltage of a power supply, additionally required by instant claim 33.

For reasons stated above, Appellant submits that instant claim 14 and its dependent claims 15-18, 20-25, 27-29, 33-37, 39, and 40 are non-obvious over Clarke in view of Selman, and further in view of Waksman, and respectfully requests the reversal of the final rejections under 35 U.S.C. § 103(a).

4. Claims 25-32 are patentable under 35 U.S.C. § 103 over Clarke in view of Selman, Waksman, and Spears.

Spears describes heating an expanded intraluminal balloon to fuse together segments of tissue fragmented during balloon angioplasty in order to prevent restenosis (Abstract). Spears does not provide any teaching that remedies the deficiency of Clarke, Selman, and Waksman with respect to instant claim 14, as discussed above in Sections 1 and 3.

First, Spears does not provide any motivation to modify Clarke such that the mucosal or the endothelial lining instead of the muscle layer is targeted by light ablation. On the contrary, Spears teaches that "thermal destruction of the smooth muscle cell provided by the subject technique prevents [hyperplasia] response" (col. 2, lns. 53-59). Second, Spears describes using laser output through optical fibers (col. 3, lns. 32-45; col. 5, lns. 43-62) or an electrical heating element (col. 9, lns. 37-43) to provide heat. Accordingly, Spears does not provide any suggestion as to how Clarke's method might be modified to ablate the mucosal or endothelial layer with UV light generated by a flash lamp as required by instant claim 14.

Moreover, Spears does not teach or suggest additional limitations recited by instant claims 31 and 32. Claim 31, in turn, depends from claim 14 and recites:

> The method of claim 14, further comprising disposing a lens comprising a lenticular pattern in a pathway of the light generated by the flash lamp.

Instant claim 32 depends from claim 31.

A lens with a lenticular pattern helps to focus or diffuse light when the lens is disposed in the light's pathway (Application, pg. 3, lns. 12-14; pg. 6, 18-20; and FIG. 1). Spears teaches how to heat the tissue, and does not teach or suggest the need for or how to focus or diffuse light, and certainly not the use of a lens with a lenticular pattern.

For reasons stated above, Appellant submits that instant claims 25-32, which each depend from instant claim 14, are non-obvious over Clarke in view of Selman and Waksman, and further in view of Spears, and respectfully requests the reversal of the final rejections under 35 U.S.C. § 103(a).

5. The claimed invention is patentable under any other possible bases for rejection.

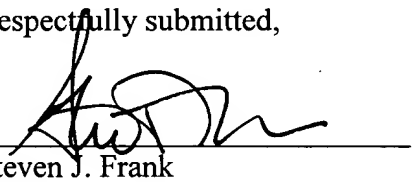
Appellant believes that the foregoing arguments address each of the pending rejections of the pending claims. In particular, the present Brief addresses each of the rejections made final in the final Office action. Accordingly, Appellant submits that the present application meets all requirements for patentability.

Conclusion

For the reasons given above, it is respectfully requested the rejections in the final Office action be reversed and the application be passed to issue with claims 14-40 as presented in the Appendix.

Because this corrected Brief on Appeal is submitted within one month from the date of the non-compliance notification, Appellant believes that no fee is due. However, the Commissioner is hereby authorized to charge any additional fees necessitated by this filing to Attorney's Deposit Account No. 20-0531.

Respectfully submitted,



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Reg. No. 33,497

Steven J. Frank
Attorney for Appellant
Testa, Hurwitz, & Thibeault, LLP
High Street Tower
125 High Street
Boston, Massachusetts 02110

Tel. No. (617) 310-8108
Fax: (617) 248-7100

Appendix

14. A method for ablating mucosal or endothelial lining, comprising:

a) providing a light device comprising a flash lamp;

b) inserting the light device inside a body near a mucosal or endothelial lining to be ablated, the mucosal or endothelial lining being on top of a muscle layer;

c) energizing the flash lamp to generate a high intensity ultraviolet light; and

d) ablating the mucosal or endothelial lining with the generated light, and avoiding causing substantial damage to the muscle layer underneath.

15. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of an esophagus.

16. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of a throat.

17. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of an intestine.

18. The method of claim 14 wherein the mucosal lining comprises a mucosal lining of a colon.

19. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a uterus.

20. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a urethra.

21. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a bladder.

22. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of an organ.

23. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a duct.

24. The method of claim 14 wherein the endothelial lining comprises an endothelial lining of a vessel.

25. The method of claim 14 further comprising disposing the light device at a distal end of an interventional device and inserting the interventional device inside the body near the mucosal or endothelial lining to be ablated.

26. The method of claim 25 further comprising transporting a fluid to the light device to dissipate heat generated by the light device.

27. The method of claim 14 further comprising characterizing a targeted portion of the mucosal or endothelial lining by transporting a dye to the mucosal or endothelial lining to stain the targeted portion and wherein the step of ablating the mucosal or endothelial lining comprises using light absorbed by the stained portion.

28. The method of claim 14 further comprising introducing a drug near the mucosal or endothelial lining and activating the drug through the light.

29. The method of claim 25 wherein the interventional device comprises an expandable balloon enclosing the light device.

30. The method of claim 29, further comprising transporting a fluid to the balloon to dissipate heat generated by the light device.

31. The method of claim 14, further comprising disposing a lens comprising a lenticular pattern in a pathway of the light generated by the flash lamp.

32. The method of claim 31 wherein the lenticular pattern comprises a fresnel pattern.

33. The method of claim 14, further comprising stepping up the voltage of a power supplied to the flash lamp.

34. The method of claim 33 wherein stepping up the voltage comprises connecting the flash lamp to a transformer.

35. The method of claim 33 wherein stepping up the voltage comprises using a separate lead connected to a foil disposed adjacent the flash lamp.

36. The method of claim 33 wherein stepping up the voltage comprises depositing a layer of metalization adjacent the flash lamp.

37. The method of claim 14 further comprising redirecting some of the light generated by the flash lamp.

38. The method of claim 37 wherein redirecting some of the light comprises using a reflector.

39. The method of claim 14 further comprising filtering the light generated by the flash lamp.

40. The method of claim 27 wherein the targeted portion of the mucosal or endothelial lining comprises a diseased portion.